NATIONAL INSTITUTES OF HEALTH

MEETING

From Data to Discoveries:

Creating a Research Program for All of Us

th

Monday, May 6 , 2019

10:00 a.m.

National Institutes of Health

Clinical Center

Building 10

Masur Auditorium

10 center Drive

Bethesda, MD 20852

REPORTED BY: KeVon Congo, Notary Public

JOB No.: 3287408

SPEAKER LIST

Stephanie DeVaney, Ph.D, Master of Ceremonies
All of Us Research Program, National Institutes of Health
Francis S. Collins, M.D., Ph.D, Director, National Institutes of Health
Ana Pavon, All of Us Research Program Participant Ambassador
Robert A. Winn, M.D. Associate Vice Chancellor for Community Based Practice
Deven McGraw, J.D., General Counsel and Chief Regulatory Officer Citizen
Elizabeth Coh, Ph.D., N.P., R.N., Rudin Professor of Community Health Hunter-Bellevue School of Nursing
David Glazer, Engineering Director, Verily
Nora D. Volkow, M.D., Director, National Institute on Drug Abuse, National Institutes of Health
Gary, Gibbons, M.D.
Eric Dishman, Director, All of Us Research Program
Vick
Unidentified Speaker from Audience
Cliff Andrews

MS. DEVANEY: Good morning. Good morning, welcome, my name is Stephanie Devaney, the Deputy Director of the All of Us Research Program, and I'm thrilled to see you all here today as we celebrate one year since we, at the All of Us Research Program launched nationally.

Welcome to all of you here in the room and everyone who is watching online. Thank you. Today is an important opportunity for us to reflect on what we've achieved, and most importantly to acknowledge the contributions of more than 230,000 participants who have already begun the process of joining our program.

Our participants currently hail from 50 states, and 80% are from communities and groups that have been historically under-represented in biomedical research.

It is this fact that makes us most proud today. Our community of dedicated researchers, participant partners, consortium members and advocates have come together to build something truly awesome.

At the same time, we recognize that this

program is still in its infancy. We have so much work yet to do from motivating one million or more individuals to become our partners, and generously share information and data about themselves, to building out key components like our genomics pipeline, including the return of genetic information to those participants who want to receive it, opening up access to researchers through our research hub.

We are furiously working to deliver what matters most to you as researchers, clinicians, participants, and our advocates. Today's program is designed to share with you the scientific possibilities that exist with a cohort and dataset of this scope and size.

You'll hear from our own Francis Collins, Eric Dishman, Nora Volkow and Gary Gibbons. We're also joined by leaders from within our consortium, coming to us from the University of Illinois at Chicago, citizens, the Hunter-Bellevue School of Nursing and Verily.

Everyone on stage today brings with them a diverse perspective informed by both our professional

achievements and our personal passion. But what brings us all together here today is our shared desire to bring fruition to precision medicine.

It is our belief that with more precise and diverse data, we can enable research that can help build a future where health disparities are reduced and entire communities who for so long have been under-represented, can be empowered.

And with that, I will pass the microphone over to a man who truly needs no introduction, our NIH Director, Doctor Francis Collins. Francis saw the value of precision medicine more than 15 years ago when he was spearheading the completion of the human genome project.

And today, his talk, the research promise of All of Us, will delve deeper into the scientific impacts of the All of Us research program. Thank you, Francis?

MR. COLLINS: Thank you Stephanie and good morning to all of you. I am delighted to be here, to celebrate this one-year anniversary of the launch of this flagship enterprise. Whether you're joining us

here on the NIH Campus, here in the Masur Auditorium, or by video, or watching the livestream all around the country through our Facebook Live connection. I think we're all eager to hear what's happened to all of us in this one-year since this nationwide launch.

I think many of you are already familiar with All of Us and its bold enterprise aiming to enroll one million Americans from all walks of life, from across the United States, asking them to volunteer their data to help find answers about any number of health conditions.

The goal is to help speed up medical research and usher us into this new era of precision medicine where prevention and treatment is no longer one size fits all but tailored to the individual.

When I look at where we are today, it is hard to believe that it was just a year ago that I stood with Dara Richardson-Heron in the Abassinian Baptist Church in Harlem, New York City for the launch -- one of the seven locations in the country where we were launching on that remarkable day.

I hoped then that many would share this

vision and help us achieve this common goal of building a research resource that would make possible the next great discoveries in health and medicine. And boy, have you answered that call. It is gratifying indeed.

More than 230,000 people across this country have started the process of joining the All of Us research program and more than 142,000 have completed the full protocol. That includes answering surveys, agreeing to share electronic health records, giving physical measurements, donating bio samples and even linking their Fitbit data.

That’s a lot of valuable data for researchers to explore and make those next great discoveries for health. And not only have we built a large research resource, but as you just heard from Stephanie, we’ve done it with partners from diverse communities. Almost 80% of the participants so far are from communities that typically have been under-represented in research and 50% are racial and ethnic minorities.

Too often such diverse communities have been left out of research and therefore left behind when

cures are discovered. So, all of us aim to make a profound commitment to understand and chip away at those vexing health disparities, that is a major part of our goal.

So, in just one year, and even though only part-way to the enrollment goal, All of Us has managed to become one of the largest, most diverse research resources in history.

I want to offer my thanks to the participants, the community partners, and the passionate research teams around the country who have made this possible.

But I want to focus today on this one-year anniversary on another important question, what is next? Well, now that we're gathering the data, what kind of research breakthroughs will all of us enable?

And how can the research community, both traditional researchers and citizens scientists help us in this next step of the All of Us journey?

Well before I pull out the crystal ball about the future of All of Us, maybe take a moment to look back in time to see if there's a precedent here.

Let’s think back to 1948, in the little down of Framingham, Massachusetts. There more than 5,000 people volunteered for a study to find answers about the mysterious growing epidemic of heart disease.

Every two years for decades, they had a physical exam, gave blood and urine samples, and answered questions about their health. Over time, their children and grandchildren joined too, ultimately, about 25,000 participants.

Because of them, we now know the big risk factors for cardiovascular disease and have saved millions of lives through new prevention strategies, development of drugs, procedures and education.

So, in some ways, All of Us is a bit like Framingham, but 40 times bigger, covering all health conditions, consisting of a much more diverse cohort, and using technologies never dreamed of in 1948.

Now, if a study of just 5,000 people could contribute to a 67% decrease in deaths from heart disease in the past several decades -- that’s what’s happened, I think it’s safe to say that the potential for All of Us is almost boundless.

So, what kind of advances might be catalyzed by this unprecedented program? For more than a year ago, the NIH convened a workshop on research priorities which helped articulate some specific applications, hundreds of them in fact, use cases we call them.

One key area discussed was diabetes. According to the CDC, more than 30 million Americans, or almost 10% of our population have type 2 diabetes and another 84 million have pre-diabetes and are likely to go on to full-blown diabetes in the future if nothing happens.

With the All of Us dataset of one million participants -- well, do the math here. We may expect about 90,000 of those participants to have diabetes, and as many as 300,000 to have evidence of pre-diabetes.

Since this program aims to follow participants for at least a decade, if not longer, some people may develop diabetes while enrolled, and others may be able to avoid the condition due to early diagnosis and effective treatment.

So, with access to the electronic health records, researchers may be able to explore early signs and symptoms and compare the effectiveness of various prevention strategies.

Since All of Us will also pull in environmental data using linkages to national databases, researchers can look into the environmental risk factors for diabetes.

And with the genomic data available, a better understanding of the genomic factors that confer risk should also emerge. I'm willing to predict that we will be able to demonstrate that what we currently call type 2 diabetes, will actually turn out to be made up of several sub-types, each with different factors for vulnerability and resilience, and with different responses to treatment.

Because All of Us isn't just about building a dataset, but also about building a community of participants who are empowered and exciting to support medical research, interested researchers will have the opportunity to invite diabetic or pre-diabetic participants to join follow-up studies.

This could give clinical researchers an opportunity to test health intervention to see if they may be effective in early detection and treatment of pre-diabetes, or in trying new interventions for those diagnosed with the disease, such things as the artificial pancreas.

Another promising area that the workshop identified was Alzheimer’s disease, a condition that all of us can agree that’s desperately in need of new insight about prevention and treatment.

Genetic sequencing and family health history can help us identify All of Us participants who may be predisposed to Alzheimer’s or other forms of dementia by following their lifestyle choices through such data items as surveys, wearable devices, recording exercise and sleep, diet diaries, and potentially even microbiome samples, we will be able to see if any of these variables can influence an individual’s risk for developing a condition.

We might even use smart phone-based assessments, of voice and speech, to see if they can help us predict the onset of Alzheimer’s or response

to treatment. And as with diabetes, when promising new treatments for high-risk individuals emerge, All of Us participants will be in an excellent position to enroll quickly -- to enroll quickly and efficiently. These are just the possibilities for two conditions.

All of Us can empower studies in many areas -- cancer, infection, mental health, vision or hearing loss, kidney disease, pain, and so much more. You'll hear more specifics from Nora Volkow and Gary Gibbons about examples of research in their domains that they envision All of Us can empower.

And I invite all of you to imagine the ways in which this resource can plead up your own research studies. So, now that I've gotten you thinking about the possibilities of the dataset, you may be wondering how you can access the data.

You'll hear more from Eric Dishman about how you can get a glimpse of this type of aggregated data that's been collected so far, starting today. But researchers will especially want to watch for the launch of the Researcher Workbench containing more data and the first set of researcher tools which will

launch this winter.

The precise timeline is dependent on the outcomes of our usability and security testing. Now when that Research Workbench is made available it will include data for upwards of 200,000 participants. It will include survey results, measurements, and electronic health record data.

I anticipate these hundreds of thousands of datapoints just by themselves, will be very useful for researchers and will lead to many interesting studies. More data, from new participants who join and from additional data collection activities, will be added, greatly increasing both the quantity and quality and diversity of the data.

I know that many of you, like me, are also eager to access additional data types such as genomics or wearables data. The All of Us team is hard at work on plans to add those data to the dataset and are targeting a launch for their inclusion in 2020.

The team is also busy building out its scientific roadmap and planning for even more data types, additional laboratory assays, new surveys or

measurements, and linkages to external datasets. Not only will All of Us continually expand the dataset, they will also be increasing and improving the analytic tools that will be available to you through the Researcher Workbench.

The All of Us team will vouch for the fact that I'm always pressuring them to go faster. They're laughing about that, but I want to point out that in fact All of Us is operating under a very bold timetable.

Most research programs of this scale don't release data until several years after they've completed enrollment of the last participant. Our attitude here is very different. The team will do everything we can to meet these bold targets.

But we have another even higher responsibility to consider. Our highest commitment must be that we make sure that data is always secure, and that we are protecting the privacy of our participants. Therefore, everything we do will be subject to rigorous security and privacy testing.

So, to conclude my part of this morning's

special event, All of Us is on a journey where the dataset will continue to grow, and the tools will become more refined. We invite you to join us early as participants and as researchers, not only so you can begin using the data for discoveries, but also so you could get input and feedback and help us design the best research platform and dataset to help us accelerate research.

Thing of all of us as a one-year old, just having learned to walk, maybe babbling a little bit, I'm sure it said something really important about precision medicine and All of Us nurturing this enterprise, trying to help this little one grow up to become an incredible contributor to the future of health in our nation and across the world.

So, I'm incredibly excited about the potential of All of Us, and I look forward to seeing how much this program can profoundly benefit the future of health.

You know it wasn't in my script, I think we probably should sing Happy Birthday to All of Us. So, all together now in the key of G, (sings Happy

Birthday). Back to you Steph.

MS. DEVANEY: Thank you Francis, we will have cake later, not purchased with appropriated funds to be sure. Thank you Francis, your vision has been the guiding force behind this program for many years since it was really just an idea in someone's head and before we fully formed and brought on the hundreds of partners and thousands of people working with us on this program across the country.

So, now I'm going to move us into our lightning talks round and this truly will be lighting talks. We have seven compelling talks from both leaders within our program and leaders from here at the National Institute of Health.

We're going to -- I'm going to introduce our first speaker and I'm very honored to introduce her. Ana Pavón is one of our participant ambassadors meaning that she has not only joined the program but has truly become a partner in the program helping to guide and shape the decisions that we make about All of Us.

Ana is a champion for rural immigrant

community in South Carolina and for her son who has experienced an emotional and difficult trial and error medical journey. I welcome Ana to the stage. Please help me to share her story.

MS. PAVÓN: Good morning, I'm Ana Pavón, one of the participant ambassadors for the All of Us research program. I'm excited to be here today to share my story with you, so you can see why I'm part of All of Us.

My family immigrated to Los Angeles when I was a year old. My mother came from a small village in Vera Cruz, Mexico. She had never been exposed to even the most basic things to the point that she didn't even know what a toaster was.

This lack of exposure translated to how we received care. Our illness were treated at home. I never say a pediatrician growing up. One day I needed dental care. My mom met a friend at church who offered dental services in his home, so that's where I went.

In 2001 I moved to South Carolina and later began working at Cooperative Health, a community

health center. This was my first real exposure to the healthcare system. The place I worked at served a rural community that included many immigrant farm workers. Because I was bilingual, I was given many responsibilities, often serving as an interpreter and a patient liaison.

One day, an adult man came in for his first dental cleaning ever. He had never before seen a dental instrument and perceived them to be torture devices. I helped ease his anxieties by asking him -- by talking him through the process.

He left the place that day knowing more about dental care, and I knew it would help his children too, as he now understood the importance of beginning early.

I was passionate about my work because I saw myself in these workers. I let them know about our programs and I tried to help the staff understand the unique needs of the community.

While I was doing this work for our community, I was struggling at home watching my son develop symptoms of a condition I knew nothing about.

In 2011 my son was 5 years old when he suddenly started walking differently, awkwardly. He was jerking around, and he described being itchy.

I took him to the doctor, the first dozen of appointments and they told me he was fine, but I knew he wasn't. So, I started to take him to Urgent Care where they gave him medications. The jerking stopped, but he developed a vocal tic and would sometimes scream randomly. This was all very new to me and very scary.

I kept taking him to the doctor who thought it was allergies and prescribed some allergy drugs. They didn't help and we wanted more answers. So, like many people, I started Googling and I came across Turrets Syndrome -- my son's symptoms being somewhat different from what I read about, so I didn't think more about it.

Eventually, the doctor referred my son to psychiatric care. It didn't feel right, but I took my son and they gave him a new medication with some pretty bad side effects. My son's condition kept worsening, he now had a hand and shoulder tic and also

started cursing and blurring out derogatory words.

At one point, the side effects from the meds made him so depressed that I thought maybe he'd be better off with the tics. It took a chance encounter for my son to be diagnosed with Turrets. His medical condition -- his medical journey has been one of trial and error where we've lost precious time and he's faced horrible side effects.

I wonder if precision medicine can one day help lessen these burdens. My son experiences motivated me to get involved with All of Us. I hope one day other parents will have a much easier experience, and I know to do this we must be included in the research.

Our population is different. Our health needs are different. We need to participate. The program wants the variety, a diverse selection of people of communities. They want to have a diverse collection of samples -- that to me, matters.

From my work with Cooperative Health, I know it won't be easy for some populations to be included. That's another reason I'm working with All of Us, so I

can help the program understand the need, culture and also the many friends of my community.

We're now at a time where we matter. This is why I believe the future of research is this. Thank you.

MR. WINN: Good morning everyone, and for those of you who know me, I will keep this in four minutes. This is a talk about why being represented matters and why actually this was a driving force for me being part of the All of Us program.

And in fact, I think I'd like to start off really what the promise of science has been. I've lived through an entire generation where we had classes about genetics, but never thought we'd actually look at the entire genome.

It's been wonderful to think about all the things I've been able to do in my lifetime in the context of seeing lung cancer patients, which as a medical student I would have to sort of say, well, there's not much we can do for you. Now, I'm being able to offer immunotherapy, molecular-targeted therapy.

I've seen it in my lifetime. We have gadgets like the one you see on this screen where you can take your cell phone, and not only get EKG's, but you could actually diagnose your own kidney stone, and who knows what other things we'll be able to do.

It's been great to sort of see that we're working in science in a way in which we can get down to the single cell and I don't know what that is, but that must be the magic fairy sort of thing. This is great.

We're down now to the single cell. We're talking about systems files. We're talking about things that we're pushing the envelope that I never thought would be possible when I was a medical student.

We're talking about big data that gets bigger every day. The interesting thing about this program though, and why I like it and why representation matters, is because what I've learned from Eric Dishman and what I've learned from Doctor Richardson Erin, is that all data matters, both big and small.

And that in our rush to get big data,

hopefully we don't make communities invisible. One example of this is if I were just to look at like expectancy in Chicago, I would sort of say, well life expectancy over the United States 79, great, in Illinois roughly 79, good.

In Chicago it's roughly 79, except for when I take a more granulated precise look. What I love about really All of Us and the precision medicine sort of program and the approach is that we want to be able to see things that we weren't able to.

In this context, you see on your right, you know, something called the loop which is where Oprah Winfrey would tend to hang out. The life expectancy there is 85 and literally that's about 3 miles away from where my cancer center is.

By the way, if I take -- go to your left which is east/west, we would go into an area called West Garfield Park. Now West Garfield Park is again about 3 miles away from Kansas Center, but has a different life expectancy -- it's 69. And to be honest with you, for record keeping, just for total transparency's sake, it's actually 68.45, but you

know, being in kindergarten and other things, I've learned how to you know, round it up to 69 because I just couldn't take 68, but that's today.

So, the promise really of this program gets beyond just the bigness of the data and gets to the functionality of the data and the impact it will have on these communities by seeing them.

So, to this, someone say yeah, but how do you get those who are under-represented into biomedical research sort of involved because this is tough business? Right, we know about Tuskegee and the 1932 United States Public Health sort of service, sort of experiments that went on that actually thought at the time that syphilis -- African Americans would be a great sort of, control group since syphilis didn't happen.

Now the reality about this program is there are lots of examples that you could go back in time, but the one example I want to actually put up there now is this -- when I actually go to the barber shop, when I go to the churches, people are also wondering about what's happening now -- the disparities that are

happening now.

And how do you get people involved? Well the first thing of getting people involved that I thought was a brilliant move of this program in particular, was to not deny that the past had happened. To say, yes, it did but guess what? We're moving forward. And the reality is you're not going to trust me by just the words I say, but by the behaviors we do every day within the program.

I'll give you one quick example. We had a group of 250 African American men on the south side of Chicago who actually volunteered to sort of say not only will we do this, but when we will get our results.

It seems like the ancestry part is actually kind of interesting. But more importantly, these same men wanted to know with the town hall that we had with them, when we get these results, I may not be helped, but how is this going to help others? That is a recurring team.

So, this myth that minorities will not participate is not so much -- it's not true, it's how

we package, how we interact, how we show up, how we gain trust is by showing up, being honest and being consistent. And this program has allowed us, particularly those people who believe that community matters up there.

Now, I've come down to my last -- all I'm going to say at this point is I'm going to tell you that I understand that there are a lot of -- a million reasons why this program might not happen, but I'm going to plead to you that it has to. This program ultimately hopefully will bring out the best in us, because when history looks at us, what I'm hoping someone will say is that we may not have gotten everything right in the beginning but we kept it on the tracks and we kept it moving for the future.

The reality is this program matters because it's getting people in areas that have never been engaged, engaged in a way and giving them hope that this will help not only them, but help their communities and help their kids. To me, this is more than just science, it really is about the health of the nation and moving it forward by what I love most

which is through science. So, with that I want to say thank you very much and I did okay, I think.

MS. MCGRAW: Those are tough acts to follow. Good morning. It is really an honor for me to be here, so pleased. I would come all the way from California to be able to be in this building and support this program.

Our infrastructure for conducting human subject research is ultimately dedicated to improving the health and well-being for all individuals. I've always thought that researchers are really dedicated to the noble cause of helping people, really through their contributions to advancing medical science, and to learning about what interventions or treatments work best in which population. That helps people.

Our research community has for a very long time, really viewed individuals as research subjects, but still also respected their interests and honored their important contributions by asking for their consent first, and through ethical review.

But the All of Us research program is forging a different path -- a path where individuals from

populations who are often missing from research datasets and who often have deep misgivings about participating in research are actively sought for their contributions.

Where individuals are asked to donate their specimens and their data for research purposes, and where individuals have an opportunity to receive some of this data back if they want, where the individuals are participants and not just data subjects.

The idea that individuals can and should be able to get their healthcare information and be able to use it and share it as they see fit is not, actually, it's not a new concept. It's an under-utilized concept, but it's not a new concept.

Since 2000, the HIPAA privacy law -- I'm continuing to move forward, since 2000, really this is almost two decades now, individuals have had the right under the HIPAA privacy rule to a complete copy of their health information. Again, to use it and share it as they see fit.

And I know a little bit about this law because I wrote extensive guidance on it when I was

the Deputy Director for HIPAA at the HHS Office for Civil Rights. HIPAA may have been one of the first laws to do this, but new privacy laws, such as the Global Data Protection Regulation in Europe and California's new Consumer Privacy Law, really doubled down on this idea and gives individuals even broader rights to their information in lots of different contexts.

Some of you may be asking why is this right to data access part of a privacy law? What do those things have to do with one another? Well, in some respects actually providing individuals with the right to the same information that everyone else has about them is in some ways justification for enabling those entities to collect the data, to be able to themselves engage in broad usage of it, both identified and in de-identified form, including for research.

In the medical context, people tell me all the time and I don't think that it's legally right, but still rhetorically has a huge amount of power which is that people frequently consider the data and medical records to really belong to the patient.

And I think most importantly, giving individuals the power of their data, it really enables them to take more control of their health and to seek better care for themselves, but also for others. As an individual, when you have your data, you're empowered to seek the care that you need.

If you're sick, you can share your data, just to try to help you find a clinical trial and you can donate your data so that the next person who is diagnosed with the illness that you have may have a better chance of surviving or a better chance at a higher quality of life.

Most healthcare for individuals happens outside of the clinical office and so enabling individuals to push their clinical data to researches and then supplement that information with data about their daily lives can really enhance research datasets and expand what we can study and learn.

Oh, and by the way, individuals can also see this data and see maybe whether it's inaccurate or not, like here are the medications I'm actually taking versus the ones that were prescribed to me, but that

I'm not taking because the side effects are really difficult for me to tolerate, or the drug is actually too expensive.

Here in the U.S., if not actually globally, we are at a real inflection point around the collection of personal data and the trust in those who are collecting it.

And part of building that trust means treating people as collaborators in caring and research and not just as subjects. The All of Us research program is showing us that there is another way.

The program is really way out in front of change that is coming. And I'm talking about change that will likely be as a result of some new laws, but also the inevitable cultural revolution that the All of Us research program is out in front of, doing the right thing before you're forced to do the right thing will always put you on the right side of history, thank you.

MS. COHN: So, good morning, oh that's great. I'm Elizabeth Cohn. I want to talk with you guys

today about some opportunities that this program affords us like no other I have seen in two decades of research with communities and that is the opportunity to think more critically and study more robustly the science of engagement.

So, as Doctor Winn pointed out, this takes place in the context of egregious acts under the name of research that have taken place in the past. And one opportunity that I saw with this program was to start to think about the ways that we could repair some of the trust that has been lost.

So, some of those include thinking about engagement models and methods. Some simple ones, like the top one, this is a Metro map, so in homage to being here in D.C., this is an engagement awareness education and engagement map that talks about how we can restore trust in communities.

So, with a hat tip to Ronnie Tepp at HBM, we can talk about starting way at the beginning, raising awareness, educating people about the purpose of clinical research, establishing ourselves as credible and trustworthy partners, creating a relationship,

supporting it and then asking for participation.

So, being in and remaining in communities in authentic ways. We can also think about a more complex model and the bottom one is from Corrine Watson, Consuela Wilkins, myself and Usha Menon. When we tried to really take apart what's inside that type of change, so how do we think about and measure context, trust and mistrust, community readiness and outreach and fairness and equity?

What are the dynamics that are taking place and how can we influence those? And then what goes into actual engagement, thinking about the integration of cultural knowledge, appropriate research design and community involvement from the ground up?

And then we really wanted to think about and develop a set of outcome measures that would point the way towards better, more robust and long-term community involvement.

So, what are some of the opportunities then to study trust, to study engagement, to study partnerships? How do we do that? What's the science behind the engagement? What you see down here are

pictures from a recent workshop that we did at Columbia University where we brought in 20 community-based organizations and partners of the research All of Us program, and sat down with them through an amazing kind of pilot study funded out of Dara Richardson-Heron's initiative.

To think about what are some ways if community organizations are doing education and outreach, and a place like the New York City Precision Medicine Consortium is doing enrollment, recruitment and retention, what do those bridges look like?

What do those relationships look like and how can we -- what are the best ways for us to do them? We listened a lot, we learned a lot, and I have to say in that afternoon we laughed a lot.

So, there are some things that we knew, like make the outcome of the research meaningful for the community, and there are some things that we didn't know, and we had a lot of time learning them and a great time.

So, I just want to end with a couple of lessons learned. I've been with the program almost 4

years now, it could be a little bit longer and so, I want to say that over time I've learned that community -- they've often said that community engagement is messy. I don't think so. I think it's just really complex.

I had the opportunity to sit in communities and talk to them about civil rights, about civic discourse, about things that have happened in the past and about our collective hope for the future.

I think that we've confronted issues of trust, of institutional and structural racism, of people's relationships with their providers. We've offered and received cultural humility, and we thought about having a presence over time in the communities in which we want to work.

And that's been ongoing for decades. We have the opportunity in this initiative, unlike any other, to study resilience over disparities and I really encourage people to think about how we can do that in a meaningful way. And done right, it can lead to empowerment and action in community health, which is what we want.

I'm not going to go through the column on the right, but I just want to say that within All of Us initiatives now and going forward, we can study things like distributive justice, empowering community advisory boards, capacity building for health in communities that are under-served and under-resourced.

We can study trust, and if we wanted to, we could study the cost and effectiveness of some recruitment of minorities, but that to me, is just another kind of way to -- another lens in which to view some of the work that we can do, thank you.

MR. GLAZER: Hello, I'm David Glazer and I have the privilege of talking about the technology that we are building to advance the goals and missions that we just have heard about.

When we build the technology platform, the first question is always what are we trying to accomplish? Who are we building it for, what problems are we trying to solve? And the first people that we listened to as we were designing and shaping the technology platform, were of course, the participants.

And many of us on the technology team are

participants. So, when we say we need and we want, we're talking both in the larger sense and about our own personal desires. And the first and loudest request was make sure that the data I'm donating is stored in a reliable way.

Make sure that this is actually -- you're honoring my donation. Second, and at least as important, probably more important, is do something with it. Make a difference, right? I'm donating this data. We heard from Ana, we've heard from many people, I'm donating this because I want to make a better future.

Make sure that the data that we are donating is widely available for appropriate us to reach the biomedical goals that we think are possible and that Doctor Collins laid out at the beginning.

And then third, and all of these are critical, third is keep our data safe from inappropriate use. So, these were the goals -- reliable, available and safe. Now, from a researcher perspective, similarly, there were a set of goals that we heard regularly.

The first goal was -- give me a powerful platform. Give me an environment that let's me use the right tools and gives me rich data and let's me use those tools to find all the possible meaning in that data.

And that's a platform that was going to grow over time. We know that on day one it will have a set of tools and then we will hear and iterate and add more.

The second thing that we saw an opportunity to in this era, is say let's make sure that the researcher platform is collaborative, that it enables to facilitate the people working together, that it avoids a world of siloed research and enables a world where we can all learn from and build on each other, which leads to reproducibility.

Let's take advantage of modern technology and say that when somebody finds an insight from the All of Us program data, that other people can build on what they've learned, can reproduce that result, extend it a little bit, apply it to new data, change the methods a little bit.

So, we wanted a powerful platform to enable collaboration and reproducibility. Given those participant goals and those researcher goals, we took an approach of saying we can now build on modern technology that has been evolving over the last 20 years and take advantage of a cloud centric approach to providing data to researchers.

Unlike the traditional approach, which always was the only choice of when a researcher wanted to work on a set of data, they would have to download a copy of that data and work on it locally, which works, but unfortunately it means that everyone’s working on their own copy in their own silo and it makes it harder to work together -- possible, but it’s harder.

We said we have an opportunity now to take a cloud centric approach where instead of bringing data to researchers, we will bring the researchers to the data. We will create an environment where researchers can work together on a shared copy of the information, share tools with each other, only collaborate if they want, but now it’s easy.

Now, when two of us want to collaborate, it’s

very easy for us to do so because we're working in a collaborative environment. So, that's the approach that we're taking. You'll all get a chance to see and there will be a booth outside afterwards where you can play with the very first taste of that, as Doctor Collins said, we're releasing the tools, the data browser, to look at the aggregate data, and you'll be able to start looking at that.

And then we're even more excited about coming up this winter to start giving the first taste of the platform that we've built that will hopefully address those goals in a way that will move research forward.

As we do that, we're looking not just at meeting the immediate goals of the program, large as they are, but saying we have an opportunity, we are part of a global community.

And I just came from a week of meetings in London, talking to national initiatives from other countries, other organizations, the globe is facing exactly the same needs and opportunities and people are advancing in different ways at different speeds with different insights.

We are designing the work we are doing with All of Us to be able to be part of that growing global ecosystem, so that over time it will be possible to build on not just the huge opportunity we have from the communities here who are donating data in America, but to allow cross-analysis, cross-sharing, cross-learning and let other projects benefit from the work we're doing and us to benefit from those.

So, we're very excited about the work we're doing, about the first taste of it that we're giving you now, and about the future, thank you.

MS. VOLKOW: Happy Birthday All of Us. It's wonderful to be given an opportunity to actually speak to you about why is it this program can be transformative to what we do at the National Institute on Drug Abuse, and I was given 7 minutes by Eric, and I am grateful for that.

I said okay, I have to choose one, so then what am I going to choose? Because the opportunities as Francis was saying, this is a resource, and what type of research it will bring about are quite vast and extensive, but I only have 7 minutes.

So, of course, what am I going to be speaking about -- the opioid crisis that we're currently living in in our country because its actually responsible for decreasing the life expectancy of Americans, despite the fact that we have an extremely solid healthcare system.

So, what is it that drove it? It drove it in a way, lack of knowledge, lack of infrastructure that started with over prescription of opioid medications for patients suffering from pain because we actually did not know how to properly treat that.

Now, did we know which patients would be at risk for overdosing, nor do we know yet, who are at risk from dying from addiction.

The second, as people became addicted to prescription opioids, we are seeing an increase in deaths from heroin, as more people started to actually find it easier to get access to heroin, as well as individuals initiating the drug use with heroin.

And more recently, the mortality has been increased by the emergency of synthetic opioids where patients becoming tolerant to heroin, surpassed only

to fentanyl with very high mortality rate. So, what drove this epidemic as I say, it came to two sides. On the one side a tremendous need of patients suffering from pain for the treatment of their condition and on the other one, high vulnerability that we have as some individuals, as some of us, an asked the country to the affects of drugs and to addiction.

In the case of pain, we actually recognize that one of the big challenges that we have is that you -- we all have suffer from pain, but just a certain percent go on to transitioning to chronic pain and there are many questions that we don’t know about who is at risk.

We know that the numbers are actually quite high, that approximately 20% of U.S. Americans are suffering from chronic pain and that comes to an estimated 5 million people.

So, if we think of All of Us, where we’re going to be collecting 1 million individuals to participate, we will end up by having 200,000 who will have chronic pain. Of those that have in the United

States, it is estimated that approximately 8% of them will suffer from high impact chronic pain, and this is pain that interferes with your everyday activities for the past six months.

We also know that if we don't treat this, the consequences are devastating. 9% of suicide descendants have evidence of chronic pain. And those, to try to advance our understanding of who's more vulnerable to chronic pain, we have information at the population level -- and the immunology has shown us that women are more vulnerable to develop chronic pain, older adults, unemployed, living in poverty, with public held insurance and world residence.

But how does that translate to the individual? So, me, as a doctor, or me, as a patient, know what would be the most sense. I'm a female, but what does that tell me more about my vulnerability?

Genetic factors are important and yet we still know very, very little about those genes that make you more vulnerable to getting to that transition from acute chronic pain.

And as you get exposed to opioid medications,

we know that approximately 10% of individuals would become addicted. But who are they? How do I actually recognize them? From the biological data of course, I have group findings. If you actually have a substance use disorder in yourself or your family, you're at much higher risk of becoming addicted.

If you have a of comorbidity psychiatric disease, you are much more likely to become addicted if you are given prescription opioids. But as an individual, how does that translate to me?

And being able to understand who's at risk of course, would lead me to maximize and tailor the intervention. And yes, genes are of extraordinary importance in addiction. 50% of the risk of vulnerability for addiction are related to genetics, but we don't understand which ones are they and how do they interact with the environment?

And this is exactly why All of Us becomes such an extraordinary opportunity for us in research. I start to -- the main initiative that we are doing at the NIH to address the opioid crisis, we have an initiative called Helping end Addiction Long-term

Initiative. It has a component devoted to research that will facilitate, accelerate our development of novel interventions for treating pain and on the other side, opioid use disorder -- accelerate development of interventions that will enable us to treat better patients that become addicted to opioids and to prevent them from overdoses.

As part of those projects, we have to dwell into large cohorts and populations. On the pain side, there will be large clinical networks to tell us the efficacy of intervention.

And on the side of the opioid use disorder, we're also developing large networks of community programs to delve into the environments and characteristics that make individuals basically on the one hand, vulnerable for pain, vulnerable for addiction, that may actually enable them to predict at one moment which one will be better, which form of this treatment, and which one will respond to the other.

To the extent that the All of Us has opened up a window to actually link this program, we will all

benefit because it will allow us to bring our findings which up to now, are very important, giving our data and compilations, to actually bring it up to the individual.

All of Us matters because it actually addresses disease for which all of us are vulnerable -- will have one vulnerability or the other. And it also matters because it is for each one of us, because it is for each one of us in isolation, and it is for each one of us all together, and it is that all together that will make ultimately the difference to develop better treatments, better preventions for each individual based on their circumstances, thank you very much.

MR. GIBBONS: Alright, well good morning. I'm Gary Gibbons, Director of National Heart Lung and Blood Institute. It's my pleasure to also participate in the celebration of the one-year anniversary of the All of Us program.

As Francis mentioned, we are privileged -- something lost in translation there, okay. We are very privileged in NHLBI that we celebrated the 70th

anniversary of the iconic Framingham Heart Study, one of the early cohorts that Francis alluded to earlier in which that iconic cohort study taught us so much about heart disease in this country.

And indeed, it’s part of a legacy of our institute in which we’ve reached out to a variety of populations to develop longitudinal cohort study of which Framingham was the forerunner, and it’s been inclusive of the diversity of our country.

And indeed, that’s one of the things that we think is complimentary about our top med program of program and precision medicine that leveraged our cohorts that include over 150,000 individuals involved in these longitudinal studies which we had deep characterization and at which at this point, we’ve garnered 150 whole genome part of that population database and includes, indeed, the Framingham study.

It compliments I think all of us in the spirit of the participant partnership that is crucial for you to have multiple generations come back yet again and again to contribute their data toward this larger good and social beneficent of participation,

but also in including a diverse set of populations.

This has created, we think, one of the larger resources in genomics that has been inclusive. Indeed, where the majority of the participants in this genomic resources are those of non-European ancestry, and we believe that this is not something that's just simply politically correct, but indeed it's scientifically driven, only because we understand the diversity of genomic variation across the human family that we'll be able to gain insights into the pathogenesis of disease that affects us all.

We were also intrigued by our complementarity. We look forward to how all of us can take things to a larger scale that we could indeed envision in a cohort, say like Framingham, 5,000 individuals and it really just stimulates the mind and imagination to think about now a cohort of a million.

And so, we're very much excited about who this toddler is going to grow up and become because it's going to enable us to ask questions that -- at scale, in a diverse population that quite frankly were unimaginable previously.

It might be able to give us insights into the dynamics of complex traits and disorders in which we know there's a dynamism, and an interactive interplay with our genome and our environment. And just I had to only pick two things to fit into the 5 minutes I had, but I thought I'd start off with one exemplar -- Sickle Cell Disease.

This is a rare disorder that affects about 100,000 African Americans in this country, though it affects every race ethnic group around the world. Indeed, millions around the world are affected by the disease.

And as Francis Collins knows, we're dedicated to curing this disorder in a transformative way in the next 5 years. I'm not here to talk about our Cure Sickle Cell Initiative, but indeed, how that variation came about.

And it reflected an environmental genomic interaction in which people of African ancestry, our genome has been shaped by that experience of our ancestors and our population history, indeed how we interacted with vectors in that environment that

caused malaria and that caused a change in our genome in ways that our body tried to defend ourselves against the complications that probably brought the survival advantage in such that a variant of the defects of the hemoglobin gene actually became advantageous and indeed, became more prevalent in those endemic areas of malaria, resulting in sickle cell traits.

And indeed, that has been thought to be a relatively benign condition. So, yes, if you have both copies of that variation, you might have Sickle Cell Disease, a rather devastating illness. But if you had only copy, that might be a good thing, protective against malaria.

And indeed, in the comfort of the United States without malaria, it will start to be a benign condition except in sort of rare, extraordinary circumstances.

But this is where cohort studies were able to tell us something about this trait which about prevalent in about 5 or 7% of African Americans that might not be quite as benign as we thought. And we

are aware of the notion that African Americans have an increased risk of chronic kidney disease, and we're still wondering what are those pre-disposing factors?

The cohort studies have taken them all together to try to get up to a little bit of scale to look at this contribution. It started to tell us that perhaps having that sickle cell straight may not have been as benign as we thought and maybe it's a predisposing factor and a contributor to health disparities, we see in chronic kidney disease and may confirm an increased risk.

Something about that micro-environment of the kidney that tends to be hypoxic and stressful to cells that might indeed promote damage in this population and explain some of those disparities.

It kind of raises the issue of what happens when you do have just one copy of something that might be deleterious, and indeed, understanding what it means to be a Heterozygote or concepts like Haploinsufficiency. What does it mean to have a certain dose of a variation that it might affect the function of a protein?

And this is something that we have hundreds of thousands of whole genomes, we're going to have an explosion of trying to understand what each of those variants does, how do they work in a dosage fashion? How do they interact with each other in ways that again, we couldn't imagine consideration years ago?

We're starting to appreciate that when it comes to complex traits, much of which will be seen in All of Us cohort, many of which are in our portfolio -- hypertension, high cholesterol, myocardial infarction, coronary disease, asthma, and other disorders -- that these different variants, some of which are influenced by our own population history and ancestry, may be coming together in combination in a way that may identify people at great risk, or might even identify those who are particularly resilient to certain environmental stressors.

This is an opportunity now that we have and is starting to emerge. Indeed, a recent study by St. Catherine's to start to look at what are those predisposing factors to heart attack? And use the Framingham risk score -- that classic iconic study

that told us how we -- physicians might predict who's at risk.

They found, by putting together the genetic variation, he was actually able to identify another high-risk group that Framingham risk score alone would not have picked up, that maybe predisposed to a heart attack. And this is now being tested in a variety of traits such as atrial fibrillation, diabetes, as Francis alluded to earlier, and this represents a whole new window of opportunity for thinking about precision prevention and personalized medicine.

These are the capabilities that we believe that the All of Us program will indeed allow us to contemplate so that while we can actually consider with the multiple dimensions, multiple modalities of data collection enabled at scale of one million, we may be able to understand how these variants interact with various environmental influence.

We start to envision a day when we know that we can predict that you'll have this irregular heartbeat predisposition called atrial fibrillation. Ordinarily, that might only become manifest when

you've come into an emergency room dizzy and short of breath with a rapid heartbeat. What if we already knew by your polygenic risk score your predisposition? What if we already knew that a personal sensor with a watch like this could be detecting your heart rhythm all along?

We might even be able to detect the first glimpses of that arrhythmia. Indeed, in ways that we might come in and actually take care of that electrical short-circuit prospectively, proactively. Or, alternatively, even if it happens, we could detect it and using artificial intelligence figure out that that is indeed a worrisome arrhythmia, and in fact press out a message, give you instructions about what you should do to treat it before you even need to go to an emergency room.

That's the vision that we have in mind and that's the capability that we think is being created by the All of Us platform. So, we're very excited about the potential for this to transform how we think about precision prevention and personalized medicine the next 5 to 10 years, and that's why we're very

excited about your birthday and what we can do collaboratively as part of this partnership with participants to really transform how we fulfill our mission to turn discovery science into the health of the nation affecting all communities. Thank you very much.

MR. DISHMAN: Good morning, I'm Eric Dishman, Director of the All of Us research program. Anybody recognize what I'm wearing? Anybody have a Sony Walkman -- the younger people in the crowd?

Here it is. Yeah, it's quite a piece of work, the Sony Walkman. I got one when I was 12. I was already starting to train to become a long-distance runner. And it has these things called -- I'll show you, for those of you who are younger. This is called a tape.

We used to make these things called mix tapes. It was a labor of love, oops, and the problem is as you were doing your mixed tape -- I was going to try to get the tape to spin out here. You know, this would happen -- oh no, right? And then all that work that you had done to build this nice romantic mix tape

for your loved one is just gone because the tap got caught in the wheels.

Now, you know, that was mobile music. It lasted for 30, 60 or 90 minutes, depending on the length of the tape. When I ran, I had to carry an extra set of batteries and a couple of tapes. If you travelled on a trip, you were carrying a whole piece of luggage with your tape collection with you.

And we could not imagine back then like what was going to be possible today, right? I had to put a picture up, because you're going to have to see it back in the audience, right? You think about the Apple ear bud today, right?

We could not imagine back then that through voice control you could have any song anywhere for very inexpensively in your pocket today, right? Or in a tiny little wireless thing that fits in your ear.

And it's not like, you know, and you think about today really the whole music industry has been transformed, and our relationship with music and our relationship with musicians has been transformed, but this did not happen overnight.

It was not from one product. It was not from one company. We often feel like these transformations have just appeared out of the blue and it just suddenly happens, but there is just a lot of continuous innovation going on that finally reached this point where it snowballed into a radical change in the way that we do things, and our relationships with the world around us.

That tape is never going to go back in there, even if you try to spin it with a little pencil, which is what you used to do. So, you know, this is kind of an innovation process, right? How do we understand needs? How do we put out early products and prototypes? How do you get community feedback? How do you iterate and improve upon those?

This is the process that the All of Us research program, as it celebrates its first birthday, is in and is trying to inculcate in the NIH environment because this process works, repeatedly, as long as you do all the parts.

Spend time with people to understand their needs, put out things early and often, even if they’re

crude or simple. When that came out, everybody said no one will ever use it, your quality of your sound is much better at home with a mounted speaker system that took up your whole living room.

No one's ever going to want it, they're toys, they're crude, they're only for the rich because they were really expensive, but over time the innovation process really drove with community feedback, innovations that now really have transformed our relationship.

So, here's another example, anybody go to this website back in July of 1995? Right, this is the Amazon original web page, right? You could go online and order a book and it would show up to your house within a week, right?

I did this, right? And this is another example where when this came out people sort of, as a joke, nobody's going to do it, why would you want to do this? A bookstore is a much more pleasant place to be. You can just run down to Barnes & Nobles.

Remember Borders, right? You used to run down to Borders and go get your book at Borders,

right? And it's the same kind of thing where crude, simple, get it out there, get community feedback, make it better and over time you start to transform our relationship to shopping, our relationship to retail, right?

And our relationship with each other through these technologies. Sometimes better for the better, sometimes for the worse, and usually both, right? This is the kind of innovation process and the way that it works.

So, a year ago today, as Doctor Collins and Doctor Richardson-Heron were standing in Abyssinian Baptist Church in New York City, I was standing in the end zone of Ford Field in Detroit. We had invited community members to come in -- that was one of our seven sites that we launched. There were many people that came into there and said I've never been in here. I've lived in Detroit all my life, but I could never afford a ticket to come to a show here or to go to a sports event.

And we were having conversations about precision medicine and engagement and getting involved

and trying to sign people up. And I was absolutely terrified. I was in part because I was standing, waiting for the feed from New York to come to Detroit and here's all these people looking at me in the stadium and I'm just shaking and waiting as I do my kind of the part of please let the satellite work.

But I was also nervous because we had just finished an alpha and a beta phase of all of our tools to start recruiting participants, and they tested pretty well and we made them better during that, but we're like is this stuff going to work? Is it even going to hold up when everybody clicks on it at the same time?

And more importantly, is anybody going to come? And we could not imagine even a year ago, that we'd be standing here today saying oh my gosh, more than 230,000 people have started the process. And we've got this amazing diversity.

I mean we had arguments at our consortium, right, saying let's just wait and see who we get, and okay, maybe we'll get 20 to 30% diverse. And we said no, no, no, we're going to try to rethink engagement

and the way that you do it with the kind of focus that you are talking about here so that we can come out of the gate focusing on the diversity.

Because we do need the science to have to have the diversity of people behind it so that the diversity of cures can exist. So, I was really nervous, and we were just taking our first baby steps. We're still improving these tools.

The participant tools have gotten slightly better, we're working on some radical improvements for the participant's portal, all based on community feedback. Put something out, engage, get the feedback, iterate and improve.

And I want to thank an amazing number of people who have done this. I want to thank each and every participant. Those of you that joined in the earliest days and those of you still joining now, our tools are pretty crude. We're not yet giving you back information, but we're working on those and testing them and getting them there.

And over time the experience is going to get better and better. But every one of you that's come

with us since the beginning has been incredibly patient and is really informing the journey that we're going on, our innovation journey as we try to improve this.

I also want to thank every single consortium member. We have a consortium of over 2,000 people from scientists to -- and researchers, to social workers, the front line staff and clinics and hospitals who this very day are out recruiting community members that are out engaging, sometimes just creating awareness in their communities of what is research.

What is biomedical research? You got to start that kind of conversation before you're trying to get people to sign on the dotted line and say hey, come donate. Come be part of history and within this program.

And standing in this building, I want to particularly thank our NIH family. The 27 institution centers have been amazing, from the leaders of those who have given great wisdom to me and to many others. I had to go to Gary and say, "Gary, what exactly is a

cohort?" I'm a guy from Silicon Valley, I know innovation process, but what is a cohort, right?

And then we have liaisons that Stephanie has been leading with all 27 institutes and centers who participated in that research priorities workshop as we start to try to develop the complex scientific road map for the next decade or more.

So, thank you to all of you for getting us to this first birthday. Now today, we're taking our first baby steps on a different innovation journey. This is starting to head down the path of at least making the cohort and the data understandable to the public and to researchers so you can at least start to get the juices flowing in thinking what might I do with that data, as I can start to understand the aggregate statistics and the kind of people who are joining the program.

So, we are launching today the beta version of our public data browser. You can go to researchallofus.org. One of our colleagues from Vanderbilt, Regina, will be out in the lobby showing them on kiosk as we get out of this room, but you can

go to it right now, researchallofus.org. If it crashes, please don't tell me, it will make me incredibly nervous. I think it's going to work, everything should be fine, but you never know, welcome to the gremlins of technology.

And this basically provides summary statistics from our ongoing database, right? So, you'll have the first curated dataset in there which is much smaller in numbers than the total people have joined, because it takes a while to collect that data, clean it, you re-identify it, curate it and make it ready for us all to see.

But those numbers will grow over time and you'll be able to see these data snapshots. So, let me just give you a little bit of a sense of it. You'll come to an overview page, up there in that search box you can type any concept that you like. I did the ones that matter to me, kidney, cancer, I did diabetes, I did Alzheimer's, all of these are sort of pervasive in my own family, and sometimes in my body.

You can click on the conditions and then you got three kinds of data right now in there, EHR data

that we're pulling in, the data from the survey questions that participants are filling out and then some of the physical measurements. And you can just click on those and start to see aggregate statistics.

For example, what are the top 10 conditions -- this is based on the EHR data, and you'll see not surprisingly, pain, as Doctor Volkow just talked about, right?

As somebody who lived with chronic kidney pain until I got my own genome sequence and got rid of my kidney cancer, I dealt with -- the issue really for me was for 15 years of my 23-year illness, was coping with that chronic pain and trying to decide each day was I going to be basically drunk at work or in pain at work because it was going to be one of those choices as you tried to figure out how to navigate that.

And it was a lot of trial and error back then as opening talks, to try to figure out what could they do for this complex individual who is kind of strange and doesn't respond to drugs like we normally see that somebody would do?

So, that's the kind of thing that you can go do, and you can start to drill down on that, right? So, we can actually go look at pain and say okay, let's look at the focus in the cohort right now by age, right, and start to look through that.

So, you'll be able to play with this and start to look at the demographic details which don't show up very well on the screen. Hopefully, you're already at researchallofus.org and starting to play with it faster than I have.

You can go into the survey explorer. So, let's understand the questions that were asked and the kind of answers and how those distribute out by age, right? Do you now smoke cigarettes every day? Some days or not at all, right? And start to get some characterization of what's going on with the people who have participated so far in our efforts.

You can also go look at the measurements, alright, so these are the physical measurements that are taken when people come in to give their bio samples. This is the mean blood pressure broken down by male and female systolic as of the current database

as we go through there.

So, just what we need now is for the community to begin to go with these early simple crude tools and start to get feedback so that we can make those better and better over time. And that is the way that the innovation process works. And the more diverse of the crowd that gives the feedback, the better, right?

Large numbers are important, but the diversity of that crowd is really important. We want to hear from participants who are trying to use this, your mom who's trying to use this and give us feedback. It's a pretty challenging tool to use right now, so you have to have a certain amount of visual literacy to be able to go get this, right, but how do we make it even easier for people and we'll be publishing reports for people who this tool proves too difficult to use, so they can still start to understand the basics of it.

Now there are some features that we already know that we want to add in. For example, at some point given the amazing diversity that we've achieved

so far, we want people to be able to sort by race and ethnicity as well as sexual and gender minorities, and sort of cut that way, but we have not added that at this point.

And why is that? It's because we're still engaging with communities to figure out how to do this the right way. One of the innovating things that we're trying to figure out as a program is how do we create an open resource but protect people's identity and data so more and more researchers in the public can access it, but at the same time how do we prevent the kind of awful stigmatizing, unethical research that often gets done with crude analysis of aggregate statistics?

So, as we speak, we're having focus groups and interactions with a wide-range of communities around the country to say what's the right balance here. They want to go sort. They said I want to know how many people from my ancestry have actually signed up for the program and what you're finding.

We're having conversations with the American Indian and Alaskan native people, right, who have been

harmed incredibly by past studies. So, we already know there's going to be new features that we want to add, but we need community input, so go to researchallofus.org, play with this data version and give us feedback.

And you can do that by going to support at researchallofus.org and click and just type in the feedback right there. This is a monitored box that we go look through and the feedback can be anything from A to Z, even misspelled something here, this is a weird way that the interface comes up to, here's how you really need to think about packaging the data to really reduce the chance of unethical research that are going to happen as we go through this.

So, as I end, and these are different places. And by the way, you can still join. We're not done with joinallofus.org, we've got a long way to go. There has been great progress in this year but if you haven't joined, you can go to joinallofus.org.

But what I sort of want you to think about is that innovation process, right? The Walkman may be silly in retrospect, but it was an innovation at the

time that started to sound the path. As a guy from Silicon Valley who spent way too much of my life working on the future of entertainment and the future of television, I want to apply these methods to the future of healthcare because we surely need to transform our relationship with the healthcare industry, with healthcare, with health and if we use these methods to engage and understand needs, put early product and prototypes out there, get feedback from the community, incorporate that feedback to iterate and improve, then we will get to the point where we transform not only medicine, but our relationship with health that can be individualized for each and every one of us, thanks for your time.

MS. DEVANEY: Thank you, Eric. You are officially on point for making a mix tape for all of us for her birthday. I would like to request “Welcome to the Jungle,” as one of the songs.

Okay, so we have about 10 minutes left, and we did -- we were intending to save some time for questions and answers. I know we packed a lot into this program today, so we want to hear from you, take

some questions. I'll ask anyone from the audience who wants to ask a question to stand up at an aisle mic, and our speakers when they answer, to come to this mic right here in the front.

I will also be taking questions from Facebook Live. We have over 1,000 people watching the event live, so thank you for all of you for joining us from where you sit across the country and know that if we don't get to your question today, our team will be answering your questions over the next couple weeks.

Okay, so we'll take our first question over here, please introduce yourself and then ask your question.

VICK: Hi there, my name is Vick and congratulations on the first year of All of Us. This question is specifically about the Heal Initiative for Doctor Volkow. And just about the level of collaboration that takes place between the Heal Initiative and other institutes, and then how it's leveraging this genetic data to more specifically develop those community-based treatments and interventions.

MS. VOLKOW: The Heal Initiative is actually an initiative where most of the NIH centers are participating and that collaboration actually is what makes it so unique because we're bringing expertise across very different domains.

As it relates to, I mean, how do we take advantage of the revolution of genetics to help accelerate our discovery? This is again an opportunity that the All of Us is opening the door for all.

So, as we're doing clinical trials, basically most of these instances, DNA is being obtained from the participants and are followed-up to try to figure out which are the genes that are going to be able to perhaps predict responses.

What's very unique too, about the issue of All of Us that I will bring, which can bring these large project together is with the healing is that it is not just uniquely that it sees that we're going off after pain or addiction because none of us is just pain or addiction, each one of us is an individual in the context of a variety of multiple conditions and

environments.

So, All of Us, by providing a platform that allows individuals to participate in a larger sample, will enable us to expand the very specifics of the Heal Initiative into a much wider arena.

VICK: Cool, thank you.

MS. DEVANEY: Thank you, I think we'll take a question from Facebook Live here and I'm going to give this first one to Liz Cohn or Rob Winn, I'll let you guys duke it out.

Minorities are least likely to participate in clinical trials. What strategies are being implemented to involve them on the front line? And then the question asker says hopefully nurses. Liz, do you want to address this?

MS. COHN: So, thank you for the question and also for the shout out for nurses. So, actually in this -- unlike any other initiative that I've ever been involved with NIH, way back about 3 years ago we started with a community partners workshop, bringing 100 people here to the NIH, while just off-site of the NIH campus to really start way back at the beginning

before the initiative, as we were beginning to just formulate it to get -- to start to get input, to start to hear people's voices about the opportunities but also the concerns.

And that community partners workshop and the continued voice at the table of community partners through genuine, authentic engagement, but also an ambassador's run by Consuelo Wilkins, at Vanderbilt and a number of roundtables that she did has continued to elevate and amplify the voice of communities to this day right now on every single committee that we have through her work and the work of others and mine as well.

There's a participant at every one of our steering committee meetings, at every one of the committee meetings, during the initiative and as we move things forward. So, even things like the publications committee, has a representative, a participant representative.

I'll speak very briefly about the New York Consortium. Our Participant and Community Advisory Board meets every other week and really is driving

some of our work in New York in a really rapid and I think, incredibly engaged fashion. Sometimes, who is leading who depends on the minute, the hour, the day, but I think we have tremendous involvement and that's one of those things that makes this initiative so very, very different from other ones. Do you want to add anything?

MS. DEVANEY: Thank you Liz. Okay, another question from Facebook Live, and this one is for Doctor Collins. What diseases will All of Us cover? Many of us have rare diseases, will this program help us?

MR. COLLINS: Well again, All of Us aims to try to enroll this incredibly diverse group across the nation, one million folks. It is therefore particularly powerful when you're talking about common diseases because you'll have lots and lots of participants who are affected.

I talked about diabetes and Alzheimer's, for a rarer disease it depends on just how rare. If you have something that affects 1 in 2 or 3,000 people, yeah, you're going to have a lot of involved

individuals, multiple sclerosis for instance. If it's a really rare disease that maybe affects about 1 in half a million people, then you're not going to have a lot of power in this study and rare disease research is really critical to NIH and it will need support in other ways than this.

Let me just say one other thing though. We are going to, because all of these million people eventually are going to have a complete analysis of their DNA sequence, we're going to uncover some surprises where people have a different spelling of a gene that we aren't quite sure what that's supposed to mean.

Those will all be pretty rare events, but because people are participants and interested in finding out about themselves, we may learn a lot about rare variants in the human genome, and what their consequences are.

So, in that regard this will be a big contributor to rare disease research.

FEMALE SPEAKER: Okay, so this question is limited to the interim intramural program, and you

know, in line with this rare disease theme. So, we have an excellent program for rare disease. Can the interim intramural investigators sort of partner with the All of Us study for sort of a follow-up of their rare disease cohorts?

So, for example, you know we have a rare disease of a family over in insufficiency and internally we had seen more than 500 patients here at NIH. Now, the resources are not there to sort of bring all of them back here for follow-up, but if we could use this mechanism in the community, patients can go and then intramural researchers can also, sort of, you know, get access to the data for those patients.

So, I'm thinking about this intramural extramural collaboration.

MS. DEVANEY: Yep, Eric.

MR. DISHMAN: So, it's a great question. I think the way I often talk about it when I'm out talking to folks at institutes and centers, both intramurally and extramurally is, there's kind of three buckets to think about collaboration with this.

And one thing I keep telling everybody is like, we're not quite ready yet, right? Because we're just trying to get the basics up and running. But one is just leveraging the resource as it is and it's intentionally designed not to be a cohort or cohorts, but at the same time there's another model that we're exploring that I sometimes call the franchised model that says, hey, if you want to run 4,000 people with this rare disease on our same platform, so that it's completely comparable to the million.

And, you know, you've got the funding to do that, we could set things up to where we could go do that. A third is just to actually then propose -- I want to do an ancillary study where I'm going to collect a whole lot more data than you did, and actually be able to bring it in there.

There's many, sort of rare disease foundations externally that have come to us saying we know that you don't want to get 20,000 people with this incredibly rare disease, and the million, but can you be a million twenty thousand and partner with us to do that?

So, we're starting to try to think through what we would need technically and policy-wise and just practically to do all those things and I think we'll get there. I don't think we're quite there as we learn how to walk and start to talk, but I think that's definitely the vision of what we're trying to get to.

MS. DEVANEY: Thank you, and I think we'll take one more question.

MR. ANDREWS: Cliff Andrews from Johns Hopkins and the Harvard Personal Genome Project. I think we're all very pleasantly surprised by the numbers after one year. What's the long-term picture you're aiming for a million, could you go beyond that and is it 10 years that you're planning to study?

MR. DISHMAN: So, I got to tell you one of the reasons I, you know, left Silicon Valley to take this job was I was like if we bring the right processes here and get good at them, I believe we can blow way past a million.

I'm not committing to it yet, we think right now at current course and speed it will take about

five and half, 2022-2023 we have different models. Well, one of the great things we don't know is we've done a great job of bringing people in with that diversity, but can we sustain it, right?

And how many more people are we going to have to over-recruit because a lot of people may drop out or may lose interest. In our first strategic objective as a program is to nurture relationships with a million or more people from all walks of life for a decade.

You know, one year in we can't tell if we're really nurturing really well. We've clearly done something different to get people in initially, because the numbers wouldn't be this high otherwise, but I think that's one of the things we have to figure out.

I think if you fast forward two or three years and we start to say hey, we've gotten really good at some of these processes, we're really confident, our analytic skills are really good. We know how to pop in to a part of the country where we have no presence and pull up clinicians and others to

be able to do the blood draws and the samples, and we really know how to sustain those people, I think that'd be great.

Right now, we don't have a lot for you as participants in there. We're trying to add some return of information, you know, late this year and even more into next year. So, there's not a huge value proposition for those who have joined yet, and I know that, and we admit that, but it also takes time to do that right.

So, I think we'll blow way past a million, but right now I'm trying to say let's stay focused on job one and then once we get good at it, we'll start surprising people when we move well beyond that.

MR. ANDREWS: Is it 10 years or longer?

MR. DISHMAN: Well, we think 5 to 6 years to get to a million, and a sustained million who have completed, you know, the continuous protocol as we go through there, but then the follow-up right, we're working now on what's going to be the follow-up. How much of the current protocol will we repeat?

If we ask people to come in and do additional

bio specimens, what additional bio specimens would we capture? People certainly talked to us about imaging. Just every time somebody comes to us with a proposal, I always say just remember, it's times a million.

Those people come to us like -- "This only costs 5,000 per person to run this thing." And it's like times a million, times a million, times a million, so sometimes we're waiting for technologies to scale to a cost where we can afford to do it for all million people as well, alright.

MS. DEVANEY: And with that, I want to thank you all for coming here in person today and for everyone who tuned in live to watch us on Facebook and the NIH video cast. I want to thank our speakers for making this symposium so rich with information and so fun.

And I want to take a moment to acknowledge the teams that are working so hard day in and day out on this program from across the country. We truly have one of the most passionate and dedicated set of folks working on this program from institutions from east to west coast and the team here at NIH who has

been working with so much dedication and passion for the past two years, and keeping it going. I want to also take a moment to acknowledge that when this program first came to be, there was no office, there was no staff, and we relied on a lot of help from folks at the institutes and centers and people just really dug in, even those who had full day jobs and became a really important set of contributors to what our program is today.

So, as you leave today, I want to take a moment to acknowledge all of those people and please take a moment to appreciate the names on the screen, thank you everyone.

(Whereupon, at 11:30 a.m. the meeting of NIH was concluded.)

CERTIFICATE OF NOTARY PUBLIC

I, KeVon Congo, the officer before whom the foregoing proceedings were taken, do hereby certify that any witness(es) in the foregoing proceedings, prior to testifying, were duly sworn; that the proceedings were recorded by me and thereafter reduced to typewriting by a qualified transcriptionist; that said digital audio recording of said proceedings are a true and accurate record to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

KEVON CONGO

Notary Public in and for the

DISTRICT OF COLUMBIA

CERTIFICATE OF TRANSCRIBER

I, HELEN VENTURINI, do hereby certify that this transcript was prepared from the digital audio recording of the foregoing proceeding, that said transcript is a true and accurate record of the proceedings to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

HELEN VENTURINI